

What is claimed is:

1. A method for predicting the risk of a disease in a subject, said method comprising:

providing an unfractionated saliva sample from said subject;

5 contacting an aliquot of said saliva with one or more lectins under conditions that allow said one or more lectins to bind to one or more lectin-binding components of said saliva;

detecting the amount of bound lectin; and

10 comparing the amount of bound lectin to the amount known to bind a saliva sample from a control subject, wherein the amount of bound lectin is indicative of the risk of said disease.

2. The method of claim 1, wherein said saliva sample is an unstimulated saliva sample.

3. The method of claim 1, wherein said lectin-binding component is an oligosaccharide.

4. The method of claim 1, wherein said lectin is selected from the group consisting of DSL, ECL, PSA, WGA, UEA, MAL I, MAA, PNA, AAL, LTL, MAL II, JAC, LEL, SNA, PTL I, ACL, GSL II, VVA, BPL, WFL, SJA, MPL, GNL, HHL, CCA, NPL, STL, PHA-L, PHA-E, GSL I, DBA, HMA, EEA, LPA, and PTL II.

20 5. The method of claim 1, wherein said lectin is not PNA.

6. The method of claim 4, wherein said lectin is MAL I.

7. The method of claim 1, wherein said one or more lectins are selected from the group consisting of AAL, LTL and UEA 1.

25 8. The method of claim 1, wherein said one or more lectins are selected from the group consisting of DSL, ECL, PSA, MAL I, PNA, AAL, LTL, MAL II, JAC, LEL, PTL I, GSL II, VVA, BPL, SJA, MPL, and CCA, and said subject is an adult.

9. The method of claim 1, wherein said one or more lectins are selected from the group consisting of ACL, PNA, LTL, PSA, MAL II, MAA, STL, PTL I, LEL, DSL, ECL, AAL, VVA, GNL I, CCA, SNA, JAC, WFL, SJA, MAL I, and BPL, and said subject is a child.

30 10. The method of claim 1, further comprising the step of assessing the risk of said disease at a defined level.

11. The method of claim 1, further comprising the step of assessing the risk of said disease as high, medium, low or very low.

12. The method of claim 1, further comprising the step of assessing the risk of future development of said disease in said subject.

5 13. The method of claim 12, wherein said assessing comprises comparing the amount of binding to a regression analysis derived from a group of subjects expressing a range of disease severity.

14. The method of claim 1, wherein said contacting step and said detecting step are part of a Western blot procedure.

10 15. The method of claim 14, wherein said procedure comprises:

applying a drop of said saliva to a matrix material; and
contacting the matrix with a solution containing said one or more lectins.

15 16. The method of claim 14, wherein said one or more lectins are coupled to a reporter selected from the group consisting of dyes, chemiluminescent compounds, enzymes, fluorescent compounds, biotin, haptens, radioluminescent compounds, and radioactive-labeled biomolecules.

17. The method of claim 14, wherein said detecting step comprises contacting the matrix with a visualizing stain.

20 18. The method of claim 15, wherein said contacting step comprises contacting the matrix with a mixture of a first set of lectins conjugated to a microparticle having a first color and a second set of lectins conjugated to a microparticle having a second color, wherein said first and second colors are distinguishable from one another.

25 19. The method of claim 18, wherein said disease is dental caries, and said first set of lectins comprises one or more lectins that are positively correlated with DFS and said second set of lectins comprises one or more lectins that are negatively correlated with DFS.

20. The method of claim 15, further comprising applying a drop of saliva from a control subject to said matrix.

30 21. The method of claim 14, wherein said procedure comprises:

applying said one or more lectins attached to the surface of a matrix material;
and

contacting the matrix material with said saliva sample under conditions that allow the lectin-binding component to bind to the one or more lectins.

22. The method of claim 21, wherein said one or more lectins comprise a first set of lectins and a second set of lectins, said first and second sets of lectins being
5 distinguishable from one another.

23. The method of claim 21, wherein said detecting step comprises contacting said matrix material with an binding partner coupled to a reporter, wherein said binding partner specifically binds said lectin-binding component.

24. The method of claim 23, wherein said binding partner is an antibody or a
10 lectin.

25. The method of claim 23, wherein said reporter is selected from the group consisting of dyes, chemiluminescent compounds, enzymes, fluorescent compounds, biotin, haptens, radioluminescent compounds, and radioactive-labeled biomolecules.

15 26. The method of claim 1, wherein said subject is a human.

27. The method of claim 1, wherein said disease is selected from the group consisting of dental caries, periodontal diseases, pulmonary diseases, respiratory diseases, cardiovascular diseases, diabetes, perinatal disorders, mucosal infections, oral cancers, pharyngeal cancers, precancerous lesions, associated autoimmune disorders,
20 HIV, and osteoporosis, and a combination thereof.

28. The method of claim 27, wherein said disease is dental caries.

29. The method of claim 28, wherein said dental caries is selected from the group consisting of early-onset dental caries, adult dental caries, root caries, DFT, DMF, DMFS, dfs, dft, dmft, dmfs, and dfs/t.

25 30. The method of claim 27, wherein said periodontal diseases are selected from the group consisting of gingivitis, adult periodontitis, and early-onset periodontitis, and a combination thereof.

31. A method of using one or more lectins for predicting the risk of a disease, said method comprising:

30 providing an unfractionated saliva sample from a subject;

providing one or more lectins that bind to one or more oligosaccharide components of said saliva;

contacting said saliva sample with said one or more lectins under conditions that allow said one or more oligosaccharide components to bind to said one or more lectins; and

5 detecting the amount of bound lectins, wherein the amount of bound lectins correlates with the risk of said disease.

32. The method of claim 31, wherein said contacting comprises:

applying a drop of said saliva sample to a matrix material; and
contacting said matrix material with a solution of said one or more lectins.

10 33. The method of claim 32, wherein said matrix material is selected from the group consisting of nitrocellulose, cotton, polyester, rayon, nylon, polyethersulfone, and polyethylene.

15 34. The method of claim 32, wherein said one or more lectins are coupled to a reporter selected from the group consisting of dyes, chemiluminescent compounds, enzymes, fluorescent compounds, biotin, haptens, radioluminescent compounds, and radioactive-labeled biomolecules.

35. The method of claim 32, wherein said detecting comprises contacting the matrix with a visualizing stain.

20 36. The method of claim 32, wherein said contacting comprises contacting the matrix with a mixture of a first set of lectins conjugated to microparticles having a first color and a second set of lectins conjugated to microparticles having a second color, wherein said first and second colors are distinguishable from one another.

25 37. The method of claim 36, wherein said disease is dental caries, and said first set of lectins comprises one or more lectins that are positively correlated with DFS and said second set of lectins comprises one or more lectins that are negatively correlated with DFS.

38. The method of claim 32, further comprising applying a drop of saliva from a control subject to said matrix.

39. The method of claim 31, wherein said contacting comprises:

30 applying said one or more lectins to said matrix material; and
contacting the matrix-bound lectins with said saliva sample.

40. The method of claim 39, wherein said detecting comprises contacting said matrix material with a binding partner coupled to a reporter, wherein said binding partner specifically binds said oligosaccharide.

5 41. The method of claim 40, wherein said binding partner is an antibody or a lectin.

42. The method of claim 40, wherein said reporter is selected from the group consisting of dyes, chemiluminescent compounds, enzymes, fluorescent compounds, biotin, haptens, radioluminescent compounds, and radioactive-labeled biomolecules.

10 43. The method of claim 31, wherein said disease is selected from the group consisting of dental caries, periodontal diseases, pulmonary diseases, respiratory diseases, cardiovascular diseases, diabetes, perinatal disorders, mucosal infections, oral cancers, pharyngeal cancers, precancerous lesions, associated autoimmune disorders, HIV, and osteoporosis, and a combination thereof.

15 44. The method of claim 43, wherein said disease is dental caries.

45. The method of claim 44, wherein said dental caries is selected from the group consisting of early-onset dental caries, adult dental caries, root caries, DFT, DMF, DMFS, dfs, dft, dmft, dmfs, and dfs/t.

20 46. The method of claim 31, further comprising the step of assessing the risk of future development of said disease in said subject.

47. The method of claim 46, wherein said assessing comprises comparing the amount of binding to a regression analysis derived from a group of subjects expressing a range of disease severity.

25 48. A method for preventing or reducing the risk of a disease, comprising:
providing an unfractionated saliva sample from a subject;
contacting an aliquot of said saliva with one or more lectins under conditions that allow said one or more lectins to bind to a lectin-binding component of said saliva;
detecting the amount of bound lectin;
comparing the amount of bound lectin to the amount known to bind a saliva
30 sample from a control subject, wherein the amount is proportional to the risk of a disease in said subject; and

administering a therapeutic reagent to said subject when the content of said component in said saliva is above or below the level contained in a normal control.

49. A kit for detecting a disease comprising:
means for collecting a saliva sample;
5 means for measuring the amount of a lectin-binding component in said sample;
and
an oral fluid standard for comparing the amount of said component in said sample.

50. The kit of claim 49, wherein said oral fluid standard comprises the 10 content of said component in said saliva of a control subject.

51. The kit of claim 49, wherein said disease is selected from the group consisting of dental caries, periodontal diseases, pulmonary diseases, respiratory diseases, cardiovascular diseases, diabetes, perinatal disorders, mucosal infections, oral cancers, pharyngeal cancers, precancerous lesions, associated autoimmune disorders, 15 HIV, osteoporosis, and a combination thereof.

52. The kit of claim 51, wherein said periodontal diseases are selected from the group consisting of gingivitis, adult periodontitis, and early-onset periodontitis, and a combination thereof.

53. The kit of claim 51, wherein said disease is dental caries.

54. The kit of claim 51, wherein said dental caries is selected from the group 20 consisting of early-onset dental caries, adult dental caries, root caries, DFT, DMF, DMFS, dfs, dft, dmft, dmfs, and dfs/t.

55. The kit of claim 49, which is a Western blot format.

56. An assay device for detecting the presence of lectin-binding components 25 in a saliva sample, said device comprising:

a sample receiving zone comprising a first matrix material for receiving an aliquot of said sample ; and

a control zone comprising a second matrix material having at least one control 30 lectin-binding compound of a known concentration bound to the surface of said second matrix material.

57. The device of claim 56, wherein said sample receiving zone matrix material is selected from the group consisting of nitrocellulose, cotton, polyester, rayon, nylon, polyethersulfone, and polyethylene.

58. The device of claim 56, wherein said sample receiving and control zones are affixed to the top side of a semi-rigid support.

59. The device of claim 58, wherein semi-rigid support comprises polypropylene, poly(vinyl chloride), propylene, or polystyrene.

60. An assay device for detecting the presence of lectin-binding components in a saliva sample, said device comprising:

10 a sample receiving zone comprising a first matrix material and one or more lectins bound to said matrix material; and

a control zone comprising a second matrix material and having at least one control saliva sample of a known concentration.

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